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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,506	12/19/2005	Andreas Meinke	SONN:085US	6550
32425 7590 03/06/2007 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			EXAMINER OGUNBIYI, OLUWATOSIN A	
			ART UNIT 1645	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/06/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.



# Office Action Summary

Application No.

10/561,506

Applicant(s)

MEINKE ET AL.

Examiner

Oluwatosin Ogunbiyi

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 36-56 is/are pending in the application.
- 4a) Of the above claim(s) 36-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/26/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.



## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group 31 claims 36-52 drawn to a hyperimmune serum reactive antigen comprising an amino acid of SEQ ID NO 91 or a fragment thereof in the reply to the restriction requirement filed 1/02/07 is acknowledged.

Claims 36-56 were pending. Claims 53-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention there being no allowable generic or linking claim.

### ***Drawings***

The drawings in this application have been accepted. No further action by Applicant is required.

### ***Specification***

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See pg.4, 49 and 57. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Information Disclosure Statement***

The information disclosure statement filed 12/26/2006 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. The documents listed in the information disclosure statement has been considered except for those not in English. An initialed copy is enclosed.



### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claim 36 be found allowable, claim 42-44, 51, 52 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.



Claims 36-42, 43-52 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to a hyperimmune serum reactive antigen of *Chlamydia pneumoniae*. The claimed invention is drawn to a product of nature. Products of nature are not patentable because they do not reflect the "hand of man" in the production of the product or manufacturing process. Applicant (s) can modify the claim to reflect the "hand of man" by reciting "an isolated or purified" provided the specification provides support for such modification.

### ***Claim Objections***

Claims 42, 44-46 and 51-52 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The claims are drawn to a hyperimmune serum reactive antigen or fragment comprising the amino acid sequence of SEQ ID 91 further defined as directed against *C. pneumoniae* infection (claims 42, 44-46) and a pharmaceutical composition comprising a hyperimmune serum reactive antigen or fragment comprising the amino acid sequence of SEQ ID 91 further defined as a vaccine (claim 51) or further defined as a vaccine for treatment and/or prevention of *C.pneumoniae* infection.

The recitation of "further defined as directed against *C. pneumoniae* infection" "further defined as a vaccine" or "further defined as a vaccine for treatment and/or prevention of *C.pneumoniae* infection" are intended use recitations which do not limit the structure of the hyperimmune serum reactive antigen or fragment or further limit the pharmaceutical composition comprising the hyperimmune serum reactive antigen or fragment.



***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising a hyperimmune serum reactive antigen comprising an amino acid sequence of SEQ ID NO:91, does not reasonably provide enablement for pharmaceutical composition comprising a hyperimmune serum reactive antigen comprising a fragment of SED ID NO: 91. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a pharmaceutical composition comprising a hyperimmune serum reactive antigen comprising a fragment of the amino acid sequence of SEQ ID NO: 91 further defined as a vaccine for treatment and/or prevention of *C. pneumoniae* infection.

The disclosure contemplates the use of the pharmaceutical composition comprising a hyperimmune serum reactive antigen comprising a fragment of SEQ ID NO 91 as a vaccine. The scope of the claims requires that the pharmaceutical composition comprising a hyperimmune serum reactive antigen comprising a fragment



of SEQ ID NO: 91 be administered to a subject as a vaccine for treatment and/or prevention of *C. pneumoniae* infection.

The specification does not provide any definition or guidance as to the structural, physical or chemical characteristics of a hyperimmune serum reactive antigen comprising a fragment of SEQ ID NO: 91 that function to induce an immune response for the treatment and/or prevention of *C.pneumoniae* infection. The recitation of "hyperimmune serum reactive antigen" does not convey a common structure or function for a hyperimmune serum reactive antigen comprising a fragment of SEQ ID NO 91 as claimed. There are no sufficient identifying characteristics of hyperimmune serum reactive antigen comprising a fragment of SEQ ID 91 that functions as a vaccine; said antigen is described only by a functional characteristic without any known or disclosed correlation between the biological function (as a vaccine) and its structural characteristics. *In re Bell* F.2d 781, 26 USPQ2d (Fed. Cir 1993).

The scope of the claims encompasses numerous structural species resulting in a highly variant genus composed of members with a significant number of structural differences e.g. a fragment of SEQ ID NO 91 ranges from a single amino acid to a plethora of different length peptides. The disclosure fails to describe the common attributes or structural characteristics that identify members of said genus and because the genus is highly variant, the function of the hyperimmune serum reactive antigen comprising SEQ ID NO 91 alone is insufficient to describe the genus of antigens comprising different length fragments of SEQ ID NO 91 that function equivalently. The general knowledge and level of skill in the art does not supplement the omitted description of a hyperimmune serum reactive antigen comprising a fragment of SEQ ID NO 91 because specific, not general guidance is needed. The specification fails to teach the amino acid sequence of at least one hyperimmune serum reactive antigen comprising a fragment of SEQ ID NO 91 that function as a vaccine to treat and/or prevent *C. pneumoniae* infection as a reference for an artisan skilled in the art to recognize fragments important for vaccine function.



The specification teaches the identification of predicted immunogenic antigens (e.g. SEQ ID NO:91) by using a screening method that uses serum from *Chlamydia* infected patients on a *C. pneumoniae* genomic expression library. The specification on p. 14 teaches that antibodies produced against *Chlamydia* by the human immune system and present in human sera are indicative of the *in vivo* expression of the antigenic proteins and their immunogenicity ... the defined epitopes, polypeptides and proteins are further to be tested in animals for their capacity to induce T cells and antibodies against the selected proteins *in vivo*. There are no examples as to whether a vaccine comprising a hyperimmune serum reactive antigen comprising a fragment of amino acid of SEQ ID NO:91 is capable of inducing an immune response (T cells, antibodies) and there is no correlation between the induction of an immune response and protective efficacy of said pharmaceutical composition for treating *C. pneumoniae* infection.

Whether the vaccine/pharmaceutical composition a hyperimmune serum reactive antigen comprising a fragment of amino acid of SEQ ID NO:91 of the instant invention will prevent *C.pneumoniae* infection is unpredictable as it is well understood that the ability of an antigen to stimulate antibody production does not necessarily correlate with the ability of the antigen to stimulate an immune response capable of protecting an animal from infection (Chandrashekar et al. US 6,248,329, June 19, 2001, column 1 line 35-40). Testing Chlamydial proteins identified by genomics and proteomics in an *in vivo* model where correlates of immunological protection can be examined provides a powerful combination for effective vaccine design (Thorpe et al. Vaccine vol. 25 p. 2252-2260, 2007). The art teaches that vaccine candidate antigens for *C. pneumoniae* are further tested in an animal model of infection to study induction of immunity and to correlate with protection from infection (Puolakkainen et al. Life Sciences vol. 322, p. 973-978 1999, Thorpe et al. Vaccine vol. 25 p. 2252-2260, 2007). The specification does not correlate production of antibodies etc with protection from Chlamydial infection.



In view of the lack of guidance presented in the specification and the absence of examples correlating the induction of an immune response to a pharmaceutical composition comprising a hyperimmune serum reactive antigen comprising a fragment of amino acid of SEQ ID NO:91 with treatment and prevention of *C.pneumoniae* infection, the unpredictability as to whether said antigen will induce an immune response and the scope of the claims, undue experimentation will be required of the skilled artisan to practice the instantly claimed invention.

Claims 42,44,46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a hyperimmune serum reactive antigen comprising the amino acid sequence of SEQ ID 91 further defined as directed against *C. pneumoniae* infection.

The term 'directed against' is vague. What does 'directed against' mean and how does this limit the antigen of the independent claim? The metes and bounds of this term are not clear as recited in the claims

#### ***Claim Rejections - 35 USC § 102 and 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.



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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 36-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Read et al. Nucleic Acids Research, vol. 28, p. 1397-1406, 2000 as evidenced by Chlamydia pneumoniae AR39 complete genome accession number AE002161 (publicly available Jan 9, 2001) and Chlamydia pneumoniae AR39 hypothetical protein CP\_0271 accession number AAF38131 (publicly available March 7, 2000).

The claims are drawn to a hyperimmune serum reactive antigen comprising an amino acid sequence of SEQ ID NO 91.

Read et al teach the genome sequence of Chlamydia pneumoniae AR39. Said genome encodes a protein that comprises the amino acid sequence of SEQ ID NO 91 as evidenced by Chlamydia pneumoniae AR39 complete genome accession number



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AE002161 and *Chlamydia pneumoniae* AR39 hypothetical protein CP\_0271 accession number AAF38131. Since the protein of Read et al and that of the instant claims is the same, the protein of Read et al will inherently be hyperimmune serum reactive.

The protein (CP\_0271) of Read et al comprises an amino acid sequence of amino acids: 4-10, 16-28, 3-14, 16-30 and 2-16 of SEQ ID NO: 91 and fragments in 9 amino acid length starting from the position 1 and 15 of SEQ ID NO: 91. Said protein disclosed by Read et al comprises at least 6, at least 8, at least 10 contiguous amino acids of SEQ ID NO: 91. As to claim 42, the recitation of further defined as directed against *C. pneumoniae* infection is an intended use of the instantly claimed hyperimmune serum reactive antigen which does not physically or chemically affect the chemical nature of said antigen (See MPEP 2111.02). Therefore, the claims are drawn to said antigen and is unpatentable over Read et al as set forth above.

2. Claims 43-48, 51-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Murdin et al. The Journal of Infectious Diseases 2000; 181 (Suppl 3):S544-51 as evidenced by as evidenced by *Chlamydia pneumoniae* AR39 complete genome accession number AE002161 (publicly available Jan 9, 2001) and *Chlamydia pneumoniae* AR39 hypothetical protein CP\_0271 accession number AAF38131 (publicly available March 7, 2000).

The claims are drawn to a pharmaceutical composition comprising a hyperimmune serum reactive antigen comprising an amino acid sequence of SEQ ID NO:91.

Murdin et al teach a pharmaceutical composition comprising heat killed *Chlamydiae pneumoniae* AR39 diluted in SPG buffer (p. S544 right column last bridging paragraph, p. S545 left column first incomplete paragraph, right column under infection protocol). The *Chlamydia pneumoniae* AR39 comprises a hyperimmune serum reactive antigen comprising an amino acid sequence of SEQ ID 91 as evidenced *Chlamydia pneumoniae* AR39 complete genome accession number AE002161 (publicly available Jan 9, 2001) and *Chlamydia pneumoniae* AR39 hypothetical protein CP\_0271



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accession number AAF38131 (publicly available March 7, 2000). *Chlamydia pneumoniae* AR39 comprises said protein as evidenced by the reactivity of infected patient's sera to said protein (instant specification pg. 3 last full sentence).

Said pharmaceutical composition further comprises at least two different hyperimmune serum reactive antigen e.g. major outer membrane protein and ADP/ATP translocase (p. S546 fig.1). Said pharmaceutical composition further comprises an immunostimulatory substance i.e. Freund's complete or incomplete adjuvant (p. S548 fig. 3).

As to claims 44 and 46 with the recitation of further defined as directed against *C. pneumoniae* and claims 51 and 52 with the recitation of further defined as a vaccine, these recitations are an intended use of the instantly claimed hyperimmune serum reactive antigen which does not physically or chemically affect the chemical nature of said antigen (See MPEP 2111.02).

Therefore, the claims are drawn to said antigen and is unpatentable over the prior art set forth above.

3. Claims 43-44, 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Read et al. Nucleic Acids Research, vol. 28, p. 1397-1406, 2000 as evidenced by *Chlamydia pneumoniae* AR39 complete genome accession number AE002161 (publicly available Jan 9, 2001) and *Chlamydia pneumoniae* AR39 hypothetical protein CP\_0271 accession number AAF38131 (publicly available March 7, 2000) in view of Meinke et al, WO 02/059148, Aug. 1 2002.

The claims are drawn to a pharmaceutical composition comprising a hyperimmune serum reactive antigen comprising an amino acid sequence of SEQ ID NO:91.

Read et al teach the genome sequence of *Chlamydia pneumoniae* AR39. Said genome encodes a protein that comprises the amino acid sequence of SEQ ID NO 91 as evidenced by *Chlamydia pneumoniae* AR39 complete genome accession number AE002161 and *Chlamydia pneumoniae* AR39 hypothetical protein CP\_0271 accession



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number AAF38131. Since the protein of Read et al and that of the instant claims is the same, the protein of Read et al will inherently be hyperimmune serum reactive.

Read et al does not teach a pharmaceutical composition comprising a hyperimmune serum reactive antigen comprising an amino acid sequence of SEQ ID NO:91.

Meinke et al teach the addition of pharmaceutically acceptable carrier and/or excipient to a composition comprising a hyperimmune serum reactive antigen (p.11-p.12). Meinke teach that said pharmaceutical preparation may contain any suitable auxiliary substances such as buffer substances, stabilizers or further active ingredients known in connection of vaccine production. Meinke teach that a preferable carrier/ or excipient is an immunostimulatory compound for further stimulating the immune response to said hyperimmune serum reactive antigen. Meinke teach said immunostimulatory compounds such as polycationic substances, especially polycationic peptides, immunostimulatory deoxynucleotides, alum, Freund's complete adjuvants, Freund's incomplete adjuvants, neuroactive compounds, especially human growth hormone, or combinations thereof.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to make a pharmaceutical preparation of the composition of Read et al as taught by Meinke et al because Meinke et al teach a pharmaceutical preparation comprising a hyperimmune serum reactive antigen and suitable carriers/excipients for making a vaccine. One will be motivated to do so because Meinke et al teach further teach that said carriers/ excipients are immunostimulatory compounds and used to further stimulate the immune response to said hyperimmune serum reactive antigen thus resulting in the instant invention with a reasonable expectation of success.

4. Claims 43-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murdin et al. The Journal of Infectious Diseases 2000; 181 (Suppl 3):S544-51 as evidenced by as evidenced by Chlamydia pneumoniae AR39 complete genome accession number AE002161 (publicly available Jan 9, 2001) and Chlamydia



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pneumoniae AR39 hypothetical protein CP\_ 0271 accession number AAF38131 (publicly available March 7, 2000) in view of Meinke et al, WO 02/059148, Aug. 1 2002.

The claims are drawn to a pharmaceutical composition comprising a hyperimmune serum reactive antigen comprising an amino acid sequence of SEQ ID NO:91.

Murdin et al teach a pharmaceutical composition comprising heat killed Chlamydiae pneumoniae AR39 diluted in SPG buffer (p. S544 right column last bridging paragraph, p. S545 left column first incomplete paragraph, right column under infection protocol). The Chlamydia pneumoniae AR39 comprises a hyperimmune serum reactive antigen comprising an amino acid sequence of SEQ ID 91 as evidenced Chlamydia pneumoniae AR39 complete genome accession number AE002161 (publicly available Jan 9, 2001) and Chlamydia pneumoniae AR39 hypothetical protein CP\_ 0271 accession number AAF38131 (publicly available March 7, 2000). Chlamydia pneumoniae AR39 comprises said protein as evidenced by the reactivity of infected patient's sera to said protein (instant specification pg. 3 last full sentence).

Said pharmaceutical composition further comprises at least two different hyperimmune serum reactive antigen e.g. major outer membrane protein and ADP/ATP translocase (p. S546 fig.1). Said pharmaceutical composition further comprises an immunostimulatory substance i.e. Freund's complete or incomplete adjuvant (p. S548 fig. 3). As to claims 44 and 46 with the recitation of further defined as directed against C. pneumoniae and claims 51 and 52 with the recitation of further defined as a vaccine, these recitations are an intended use of the instantly claimed hyperimmune serum reactive antigen which does not physically or chemically affect the chemical nature of said antigen (See MPEP 2111.02).

Murdin et al does not teach other immunostimulatory substances.

Meinke et al teach that a preferable carrier/ or excipient is an immunostimulatory compound for further stimulating the immune response to a hyperimmune serum reactive antigen (p.11 – p.12). Meinke teach said immunostimulatory compounds such as polycationic substances, especially polycationic peptides, immunostimulatory



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deoxynucleotides, alum, Freund's complete adjuvants, Freund's incomplete adjuvants, neuroactive compounds, especially human growth hormone, or combinations thereof.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to use other immunostimulatory substances in the pharmaceutical preparation of Murdin et al as taught by Meinke et al because Meinke et al teach a pharmaceutical preparation comprising a hyperimmune serum reactive antigen and suitable carriers/excipient for making a vaccine. Meinke et al teach further teach said carriers/ excipient are immunostimulatory compounds (as set forth above) which are used to further stimulate the immune response to said hyperimmune serum reactive antigen thus resulting in the instant invention with a reasonable expectation of success.

### ***Status of the Claims***

All claims are rejected.

### ***Conclusion***

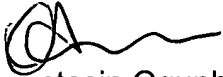
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Examiner Jeffery Siew can be reached on 571-272-0787.



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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Oluwatosin Ogunbiyi

Examiner

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PATRICIA A. DUFFY  
PRIMARY EXAMINER